Enforcement Report - Week of May 11, 2022

Class II Drugs Event

Event ID:
89916

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/31/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/03/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Lupin Pharmaceuticals Inc.
Harborplace Tower 111 S Calvert St Fl 21st
Baltimore MD United States

Distribution Pattern:
Product was distributed nationwide

Associated Products

Product Description:
Losartan Potassium Tablets USP, 25 mg, a) 90-count bottles (NDC# 68180-376-03), b) 1000-count bottles (NDC# 68180-376-09), Rx Only, Manufactured By: Lupin Limited, Pithampur, India, MFG For: Lupin Pharmaceuticals, Inc. Baltimore, Maryland 21202, USA.

Product Quantity:
657,336 bottles

Reason for Recall:
CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits

Recall Number:
D-0838-2022

Code Information:
H001333, exp. date Nov-22 H002786, exp. date Jan-23 H101282, exp. date Feb-23 H001189, exp. date Nov-22 H002955, exp. date Jan-23 H101285, exp. date Feb-23 H001714, exp. date Dec-22 H000523, exp. date Jan-23 H101989, exp. date Mar-23 H001940, exp. date Dec-22 H003080, exp. date Jan-23 H101789, exp. date Mar-23 H002388, exp. date Jan-23 H100109, exp. date Feb-23 H002389, exp. date Jan-23 H100642, exp. date Feb-23 H000848, exp. date Nov-22, H002002, exp. date Dec-22 H100110, exp. date Feb-23 H001190, exp. date Nov-22 H002003, exp. date Dec-22 H100111, exp. date Feb-23 H001191, exp. date Nov-22 H002489, exp. date Jan-23 H100146, exp. date Feb-23 H001192, exp. date Nov-22 H002390, exp. date Jan-23 H100147, exp. date Feb-23 H001058, exp. date Nov-22 H002486, exp. date Jan-23 H101283, exp. date Feb-23 H000985, exp. date Nov-22 H002487, exp. date Jan-23 H101284, exp. date Feb-23 H001059, exp. date Nov-22 H002488, exp. date Jan-23 H100643, exp. date Feb-23 H001275, exp. date Nov-22 H002787, exp. date Jan-23 H100644, exp. date Mar-23 H001715, exp. date Dec-22 H002957, exp. date Jan-23 H100869, exp. date Mar-23 H001716, exp. date Dec-22 H002958, exp. date Jan-23 H101990, exp. date Mar-23 H001717, exp. date Dec-22 H003079, exp. date Jan-23 H101991, exp. date Mar-23 H001718, exp. date Dec-22 H003121, exp. date Feb-23 H101992, exp. date Mar-23 H001941, exp. date Dec-22 H003122, exp. date Feb-23 H000847, exp. date Nov 2022

Product Description:
Losartan Potassium Tablets USP, 50 mg, a) 90-count bottles (NDC# 68180-377-03), b) 1000-count bottles (NDC# 68180-377-09), Rx Only, Manufactured By: Lupin Limited, Pithampur, India, MFG For: Lupin Pharmaceuticals, Inc. Baltimore, Maryland 21202, USA.

Product Quantity:
1,466,150 bottles

Reason for Recall:
CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits

Recall Number:
D-0839-2022

Code Information:
H903720, exp. date Oct-22 H001876, exp. date Dec-22 H003002, exp. date Jan-23 H903774, exp. date Oct-22 H001877, exp. date Dec-22 H003003, exp. date Feb-23 H000849, exp. date Nov-22 H002127, exp. date Dec-22 H003004, exp. date Feb-23 H001412, exp. date Nov-22 H002128, exp. date Dec-22 H003123, exp. date Feb-23 H001413, exp. date Nov-22 H002643, exp. date Jan-23 H003124, exp. date Feb-23 H001414, exp. date Nov-22 H002644, exp. date Jan-23 H101129, exp. date Feb-23 H001430, exp. date Nov-22 H002645, exp. date Jan-23 H101147, exp. date Mar-23 H001526, exp. date Dec-22 H002839, exp. date Jan-23 H102139, exp. date Mar-23 H001652, exp. date Dec-22 H002840, exp. date Jan-23 H102158, exp. date Mar-23 H000605, exp. date Jan-23 H001599, exp. date Dec-22 H100148, exp. date Feb-23 H001401, exp. date Nov-22 H001875, exp. date Dec-22 H102043, exp. date Mar-23 H001063, exp. date Nov-22 H002126, exp. date Dec-22 H101495, exp. date Mar-23 H001188, exp. date Nov-22 H002838, exp. date Jan-23 H001455, exp. date Nov-22 H002642, exp. date Jan-23

Product Description:
Losartan Potassium Tablets USP, 100 mg, a) 90-count bottles (NDC# 68180-378-03), b) 1000-count bottles (NDC# 68180-378-09), Rx Only, Manufactured By: Lupin Limited, Pithampur, India, MFG For: Lupin Pharmaceuticals, Inc. Baltimore, Maryland 21202, USA.

Product Quantity:
1,247,067 bottles

Reason for Recall:
CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits

Recall Number:
D-0840-2022

Code Information:
H903573, exp. date Oct-22 H002311, exp. date Dec-22 H100713, exp. date Mar-23 H001060, exp. date Nov-22 H002620, exp. date Jan-23 H100714, exp. date Mar-23 H001456, exp. date Nov-22 H002313, exp. date Jan-23 H100934, exp. date Mar-23 H001457, exp. date Nov-22 H002490, exp. date Jan-23 H100935, exp. date Mar-23 H001470,, exp. date Nov-22 H002842, exp. date Jan-23 H101081, exp. date Mar-23 H001484, exp. date Dec-22 H002843, exp. date Jan-23 H101148, exp. date Mar-23 H001485, exp. date Dec-22 H002995, exp. date Jan-23 H101639, exp. date Mar-23 H001708, exp. date Dec-22 H003199, exp. date Feb-23 H101480, exp. date Mar-23 H002314, exp. date Dec-22 H003200, exp. date Feb-23 H101822, exp. date Mar-23 H001709, exp. date Dec-22 H100028, exp. date Feb-23 H101481, exp. date Mar-23 H002001, exp. date Dec-22 H100712, exp. date Feb-23 H102288, exp. date Mar-23 H001991, exp. date Dec-22 H100221, exp. date Feb-23 H002000, exp. date Dec-22 H100222, exp. dateFeb-23 H903582, exp. date Oct-22 H001707, exp. dateDec-22 H100220, exp. date Feb-23 H000556,, exp. date Nov-22 H003045, exp. date Dec-22 H100901, exp. date Mar-23 H000557, exp. date Nov-22 H002391, exp. date Dec-22 H101078, exp. date Mar-23 H001061, exp. date Nov-22 H002312, exp. date Jan-23 H101479, exp. date Mar-23 H001062, exp. date Nov-22 H002517, exp. date Jan-23 H101496, exp. date Mar-23 H001431, exp. date Nov-22 H002841, exp. date Jan-23 H101821, exp. date Mar-23 H002341, exp. date Nov-22 H003044, exp. date Feb-23 H102286, exp. date Mar-23 H001706, exp. date Dec-22 H003198, exp. date Feb-23 H102287, exp. date Mar-23

Product Description:
Losartan Potassium and Hydrochlorothiazide Tablets USP, 50 mg/12.5 mg a) 30-count bottles (NDC# 68180-215-06) b) 90-count bottles (NDC# 68180-215-09), Rx Only, Manufactured By: Lupin Limited, Pithampur, India, MFG For: Lupin Pharmaceuticals, Inc. Baltimore, Maryland 21202, USA.

Product Quantity:
1,214,016 bottles

Reason for Recall:
CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits

Recall Number:
D-0841-2022

Code Information:
Lot # H001149 4/30/2022 68180-215-06 H001602 5/31/2022 68180-215-06 H001884 6/30/2022 68180-215-06 H002539 8/31/2022 68180-215-06 H100944 4/30/2023 68180-215-06 H101054 4/30/2023 68180-215-06 H001150 4/30/2022 68180-215-09 H001151 4/30/2022 68180-215-09 H001152 4/30/2022 68180-215-09 H001532 5/31/2022 68180-215-09 H001533 5/31/2022 68180-215-09 H001534 5/31/2022 68180-215-09 H001535 5/31/2022 68180-215-09 H001536 5/31/2022 68180-215-09 H001603 5/31/2022 68180-215-09 H001604 5/31/2022 68180-215-09 H001605 5/31/2022 68180-215-09 H001606 5/31/2022 68180-215-09 H001607 5/31/2022 68180-215-09 H001608 5/31/2022 68180-215-09 H001885 6/30/2022 68180-215-09 H001886 6/30/2022 68180-215-09 H001887 6/30/2022 68180-215-09 H001888 6/30/2022 68180-215-09 H002171 7/31/2022 68180-215-09 H002172 7/31/2022 68180-215-09 H002173 7/31/2022 68180-215-09 H002174 7/31/2022 68180-215-09 H002175 7/31/2022 68180-215-09 H002540 8/31/2022 68180-215-09 H002541 8/31/2022 68180-215-09 H002542 8/31/2022 68180-215-09 H002543 8/31/2022 68180-215-09 H002544 8/31/2022 68180-215-09 H002545 8/31/2022 68180-215-09 H002976 10/31/2022 68180-215-09 H002977 10/31/2022 68180-215-09 H002978 10/31/2022 68180-215-09 H003131 11/30/2022 68180-215-09 H003132 11/30/2022 68180-215-09 H003133 11/30/2022 68180-215-09 H003134 11/30/2022 68180-215-09 H003135 11/30/2022 68180-215-09 H003136 11/30/2022 68180-215-09 H100302 1/31/2023 68180-215-09 H100303 1/31/2023 68180-215-09 H100304 1/31/2023 68180-215-09 H100340 1/31/2023 68180-215-09 H100341 1/31/2023 68180-215-09 H100657 2/28/2023 68180-215-09 H100658 2/28/2023 68180-215-09 H100659 2/28/2023 68180-215-09 H100660 2/28/2023 68180-215-09 H100661 2/28/2023 68180-215-09 H100662 2/28/2023 68180-215-09 H100945 4/30/2023 68180-215-09 H100946 4/30/2023 68180-215-09 H101051 4/30/2023 68180-215-09 H101052 4/30/2023 68180-215-09 H101053 4/30/2023 68180-215-09

H101055 4/30/2023 68180-215-09 H101056 4/30/2023 68180-215-09 H101057 4/30/2023 68180-215-09 H101058 4/30/2023 68180-215-09 H101286 5/31/2023 68180-215-09 H101287 5/31/2023 68180-215-09 H101288 5/31/2023 68180-215-09 H101289 5/31/2023 68180-215-09 H101581 6/30/2023 68180-215-09 H101582 6/30/2023 68180-215-09 H101583 6/30/2023 68180-215-09 H101584 7/31/2023 68180-215-09 H101585 7/31/2023 68180-215-09 H101790 7/31/2023 68180-215-09 H101791 7/31/2023 68180-215-09 H102078 8/31/2023 68180-215-09 H102079 8/31/2023 68180-215-09 H102080 9/30/2023 68180-215-09 H102118 9/30/2023 68180-215-09 H102119 9/30/2023 68180-215-09 H102120 9/30/2023 68180-215-09 H102125 9/30/2023 68180-215-09 H102126 9/30/2023 68180-215-09

Product Description:
Losartan Potassium and Hydrochlorothiazide Tablets USP, 100 mg/25 mg a) 30-count bottles (NDC# 68180-217-06) b) 90-count bottles (NDC# 68180-217-09), Rx Only, Manufactured By: Lupin Limited, Pithampur, India, MFG For: Lupin Pharmaceuticals, Inc. Baltimore, Maryland 21202, USA

Product Quantity:
303,696 bottles

Reason for Recall:
CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits

Recall Number:
D-0842-2022

Code Information:
Lot # H001156 4/30/2022 68180-217-06 H001627 5/31/2022 68180-217-06 H001947 6/30/2022 68180-217-06 H002242 8/31/2022 68180-217-06 H101826 7/31/2023 68180-217-06 H001155 4/30/2022 68180-217-09 H001355 5/31/2022 68180-217-09 H001356 5/31/2022 68180-217-09 H001357 5/31/2022 68180-217-09 H001358 5/31/2022 68180-217-09 H001359 5/31/2022 68180-217-09 H001371 5/31/2022 68180-217-09 H001372 5/31/2022 68180-217-09 H001373 5/31/2022 68180-217-09 H001374 5/31/2022 68180-217-09 H001375 5/31/2022 68180-217-09 H001628 5/31/2022 68180-217-09 H001629 5/31/2022 68180-217-09 H001630 6/30/2022 68180-217-09 H001645 6/30/2022 68180-217-09 H001646 6/30/2022 68180-217-09 H001647 6/30/2022 68180-217-09 H001798 6/30/2022 68180-217-09 H001799 6/30/2022 68180-217-09 H001882 6/30/2022 68180-217-09 H001883 6/30/2022 68180-217-09 H001948 6/30/2022 68180-217-09 H001949 6/30/2022 68180-217-09 H001985 6/30/2022 68180-217-09 H001986 6/30/2022 68180-217-09 H001987 7/31/2022 68180-217-09 H001988 7/31/2022 68180-217-09 H001989 7/31/2022 68180-217-09 H001990 7/31/2022 68180-217-09 H002243 8/31/2022 68180-217-09 H002244 8/31/2022 68180-217-09 H002245 8/31/2022 68180-217-09 H002315 8/31/2022 68180-217-09 H002316 8/31/2022 68180-217-09 H002317 8/31/2022 68180-217-09 H002318 8/31/2022 68180-217-09 H002319 8/31/2022 68180-217-09 H002320 8/31/2022 68180-217-09 H002321 8/31/2022 68180-217-09 H002322 8/31/2022 68180-217-09 H002323 8/31/2022 68180-217-09 H002324 8/31/2022 68180-217-09 H002632 9/30/2022 68180-217-09 H002633 9/30/2022 68180-217-09 H002634 9/30/2022 68180-217-09 H002635 9/30/2022 68180-217-09 H002636 9/30/2022 68180-217-09 H002765 9/30/2022 68180-217-09 H002766 9/30/2022 68180-217-09 H002767 9/30/2022 68180-217-09 H002768 9/30/2022 68180-217-09 H002769 9/30/2022 68180-217-09 H002770 9/30/2022 68180-217-09 H003194 11/30/2022 68180-217-09 H003195 11/30/2022 68180-217-09 H100009 12/31/2022 68180-217-09 H100010 12/31/2022 68180-217-09 H100021 12/31/2022 68180-217-09 H100022 12/31/2022 68180-217-09 H100023 12/31/2022 68180-217-09 H100029 12/31/2022 68180-217-09 H100030 12/31/2022 68180-217-09 H100342 1/31/2023 68180-217-09 H100343 1/31/2023 68180-217-09 H100344 1/31/2023 68180-217-09 H100345 1/31/2023 68180-217-09 H100346 1/31/2023 68180-217-09 H100374 1/31/2023 68180-217-09 H100375 1/31/2023 68180-217-09 H100376 1/31/2023 68180-217-09 H100377 1/31/2023 68180-217-09 H100378 1/31/2023 68180-217-09 H100452 1/31/2023 68180-217-09 H100453 1/31/2023 68180-217-09 H100454 2/28/2023 68180-217-09 H100458 2/28/2023 68180-217-09 H100459 2/28/2023 68180-217-09 H100652 2/28/2023 68180-217-09 H100653 2/28/2023 68180-217-09 H100654 2/28/2023 68180-217-09 H100655 2/28/2023 68180-217-09 H100656 2/28/2023 68180-217-09 H100687 2/28/2023 68180-217-09 H100688 2/28/2023 68180-217-09 H100689 2/28/2023 68180-217-09 H100703 2/28/2023 68180-217-09 H100704 2/28/2023 68180-217-09 H100891 3/31/2023 68180-217-09 H100892 3/31/2023 68180-217-09 H100902 3/31/2023 68180-217-09 H100903 3/31/2023 68180-217-09 H100904 3/31/2023 68180-217-09 H100905 3/31/2023 68180-217-09 H100936 3/31/2023 68180-217-09 H100937 3/31/2023 68180-217-09 H100938 3/31/2023 68180-217-09 H101153 5/31/2023 68180-217-09 H101154 5/31/2023 68180-217-09 H101155 5/31/2023 68180-217-09 H101156 5/31/2023 68180-217-09 H101157 5/31/2023 68180-217-09 H101158 5/31/2023 68180-217-09 H101159 5/31/2023 68180-217-09 H101294 5/31/2023 68180-217-09 H101295 5/31/2023 68180-217-09 H101296 5/31/2023 68180-217-09 H101297 5/31/2023 68180-217-09 H101325 5/31/2023 68180-217-09 H101326 6/30/2023 68180-217-09 H101327 6/30/2023 68180-217-09 H101328 6/30/2023 68180-217-09 H101349 6/30/2023 68180-217-09 H101350 6/30/2023 68180-217-09 H101351 6/30/2023 68180-217-09 H101352 6/30/2023 68180-217-09 H101482 6/30/2023 68180-217-09 H101483 6/30/2023 68180-217-09 H101606 7/31/2023 68180-217-09 H101618 7/31/2023 68180-217-09 H101619 7/31/2023 68180-217-09 H101620 7/31/2023 68180-217-09 H101621 7/31/2023 68180-217-09 H101827 7/31/2023 68180-217-09 H101828 7/31/2023 68180-217-09 H101829 7/31/2023 68180-217-09 H101857 7/31/2023 68180-217-09 H101858 7/31/2023 68180-217-09 H101911 7/31/2023 68180-217-09 H101912 7/31/2023 68180-217-09 H101913 7/31/2023 68180-217-09 H102455 10/31/2023 68180-217-09 H102456 10/31/2023 68180-217-09 H102457 10/31/2023 68180-217-09 H102458 10/31/2023 68180-217-09 H102485 10/31/2023 68180-217-09 H102489 10/31/2023 68180-217-09 H102490 10/31/2023 68180-217-09 H102491 10/31/2023 68180-217-09

Product Description:
Losartan Potassium and Hydrochlorothiazide Tablets USP, 100 mg/12.5 mg a) 30-count bottles (NDC# 68180-216-06) b) 90-count bottles (NDC# 68180-216-09), Rx Only, Manufactured By: Lupin Limited, Pithampur, India, MFG For: Lupin Pharmaceuticals, Inc. Baltimore, Maryland 21202, USA

Product Quantity:
2,361,924 bottles

Reason for Recall:
CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits

Recall Number:
D-0843-2022

Code Information:
Lot # H001878 6/30/2022 68180-216-06 H002178 7/31/2022 68180-216-06 H002626 9/30/2022 68180-216-06 H102149 9/30/2023 68180-216-06 H001600 5/31/2022 68180-216-09 H001601 5/1/2022 68180-216-09 H001625 5/31/2022 68180-216-09 H001626 5/31/2022 68180-216-09 H001794 6/30/2022 68180-216-09 H001795 6/30/2022 68180-216-09 H001796 6/30/2022 68180-216-09 H001797 6/30/2022 68180-216-09 H001879 6/30/2022 68180-216-09 H001880 6/30/2022 68180-216-09 H001881 6/30/2022 68180-216-09 H001942 6/30/2022 68180-216-09 H001943 6/30/2022 68180-216-09 H001944 6/30/2022 68180-216-09 H001945 6/30/2022 68180-216-09 H001946 6/30/2022 68180-216-09 H002179 7/31/2022 68180-216-09 H002180 7/31/2022 68180-216-09 H002181 8/31/2022 68180-216-09 H002182 8/31/2022 68180-216-09 H002183 8/31/2022 68180-216-09 H002237 8/31/2022 68180-216-09 H002238 8/31/2022 68180-216-09 H002239 8/31/2022 68180-216-09 H002240 8/31/2022 68180-216-09 H002241 8/31/2022 68180-216-09 H002627 9/30/2022 68180-216-09 H002628 9/30/2022 68180-216-09 H002629 9/30/2022 68180-216-09 H002630 9/30/2022 68180-216-09 H002631 9/30/2022 68180-216-09 H002979 11/30/2022 68180-216-09 H002980 11/30/2022 68180-216-09 H002981 11/30/2022 68180-216-09 H002982 11/30/2022 68180-216-09 H002983 11/30/2022 68180-216-09 H100112 12/31/2022 68180-216-09 H100113 12/31/2022 68180-216-09 H100114 12/31/2022 68180-216-09 H100115 12/31/2022 68180-216-09 H100116 12/31/2022 68180-216-09 H100156 12/31/2022 68180-216-09 H100157 12/31/2022 68180-216-09 H100622 2/28/2023 68180-216-09 H100623 2/28/2023 68180-216-09 H100624 2/28/2023 68180-216-09 H100625 2/28/2023 68180-216-09 H100626 2/28/2023 68180-216-09 H100627 2/28/2023 68180-216-09 H100628 2/28/2023 68180-216-09 H100629 2/28/2023 68180-216-09 H100939 4/30/2023 68180-216-09 H100940 4/30/2023 68180-216-09 H100941 4/30/2023 68180-216-09 H100942 4/30/2023 68180-216-09 H100943 4/30/2023 68180-216-09 H101094 5/31/2023 68180-216-09 H101095 5/31/2023 68180-216-09 H101096 5/31/2023 68180-216-09 H101097 5/31/2023 68180-216-09 H101098 5/31/2023 68180-216-09 H101151 5/31/2023 68180-216-09 H101152 5/31/2023 68180-216-09 H101290 5/31/2023 68180-216-09 H101291 5/31/2023 68180-216-09 H101292 5/31/2023 68180-216-09 H101293 5/31/2023 68180-216-09 H101323 5/31/2023 68180-216-09 H101324 5/31/2023 68180-216-09 H101823 7/31/2023 68180-216-09 H101824 7/31/2023 68180-216-09 H101825 7/31/2023 68180-216-09 H101853 8/31/2023 68180-216-09 H101854 8/31/2023 68180-216-09 H101855 8/31/2023 68180-216-09 H101856 8/31/2023 68180-216-09 H102127 9/30/2023 68180-216-09 H102128 9/30/2023 68180-216-09 H102129 9/30/2023 68180-216-09 H102130 9/30/2023 68180-216-09 H102150 9/30/2023 68180-216-09 H102151 9/30/2023 68180-216-09 H102152 9/30/2023 68180-216-09 H102153 9/30/2023 68180-216-09 H102154 9/30/2023 68180-216-09 H102155 9/30/2023 68180-216-09 H102201 9/30/2023 68180-216-09 H102223 9/30/2023 68180-216-09 H102268 9/30/2023 68180-216-09 H102269 9/30/2023 68180-216-09 H102270 9/30/2023 68180-216-09 H102271 9/30/2023 68180-216-09

Class II Drugs Event

Event ID:
89986

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/21/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/05/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
McKesson Corporation dba McKesson Drug Company
4853 Crumpler Rd
Memphis TN United States

Distribution Pattern:
Nationwide in the United States including Guam and the Northern Mariana Islands.

Associated Products

Product Description:
Halobetasol Propionate Ointment 0.05% Net Wt., 50 gram tube, Rx Only, Manufactured by: Teligent Pharma, Inc. Buena, NJ 08310, Distributed by: McKesson Corporation dba Sky Packaging 4071 Southridge Blvd., Suite 101 Memphis, TN 38141, NDC 63739-998-67

Product Quantity:
13, 200 tubes

Reason for Recall:
CGMP Deviations: all products within expiry are being recalled because the manufacturing firm, Teligent Pharma, Inc.is discontinuing its stability study program.

Recall Number:
D-0847-2022

Code Information:
Lots: 15720, Exp.: 06/30/2022; 16449 Exp.: 02/28/2023; 16450, Exp.: 02/26/2023

Product Description:
Lidocaine Hydrochloride Topical Solution USP 4% (40 mg/mL), 50 mL bottle, Rx only, Manufactured by: Teligent Pharma, Inc. Buena, NJ 08310 Distributed by: McKesson Corporation dba Sky Packaging 4071 Southridge Blvd., Suite 101 Memphis, TN 38141, NDC 63739-977-64

Product Quantity:
81,757 bottles

Reason for Recall:
CGMP Deviations: all products within expiry are being recalled because the manufacturing firm, Teligent Pharma, Inc.is discontinuing its stability study program.

Recall Number:
D-0848-2022

Code Information:
Lots: 15597, Exp.: 05/31/2023; 16305, Exp.: 12/23/2023; 16334, Exp.: 01/31/2024; 16340, Exp.: 01/31/2024; 16346 Exp.: 01/31/2024; 16356, Exp.: 01/31/2024; 16357, Exp.: 01/31/2024

Product Description:
Lidocaine Prilocaine Cream USP, 2.5%/2.5% Net Wt. 30 gram tube, Rx Only, Distributed by: McKesson Corporation dba Sky Packaging 4971 Southridge Blvd., Suite 101 Memphis, TN 38141 Manufactured by: Teligent Pharma, Inc., Buena, NJ 08310, NDC 63739-054-66

Product Quantity:
1176 tubes

Reason for Recall:
CGMP Deviations: all products within expiry are being recalled because the manufacturing firm, Teligent Pharma, Inc.is discontinuing its stability study program.

Recall Number:
D-0849-2022

Code Information:
Lot: 16876, Exp.: 05/31/2023

Product Description:
Betamethasone Dipropionate Ointment USP, 0.05%* (Augmented) (Potency expressed as betamethasone), 15 gram tube, Rx Only, Manufactured by: Teligent Pharma, Inc. Buena, NJ 08310, Distributed by: McKesson Corporation dba Sky Packaging 4971 Southridge Blvd., Suite 101 Memphis, TN 38141, NDC 63739-996-65

Product Quantity:
55,440 tubes

Reason for Recall:
CGMP Deviations: all products within expiry are being recalled because the manufacturing firm, Teligent Pharma, Inc.is discontinuing its stability study program.

Recall Number:
D-0850-2022

Code Information:
Lot: 15644, Exp.: 05/31/2022

Product Description:
Erythromycin Topical Gel USP, 2%, Net Wt 60 g tube, Rx only, Manufactured by: Teligent Pharma, Inc. Buena, NJ 08310 Distributed by: McKesson Corporation dba Sky Packaging 4971 Southridge Blvd., Suite 101 Memphis, TN 38141, NDC 63739-053-68

Product Quantity:
5,640 tubes

Reason for Recall:
CGMP Deviations: all products within expiry are being recalled because the manufacturing firm, Teligent Pharma, Inc.is discontinuing its stability study program.

Recall Number:
D-0851-2022

Code Information:
Lot: 15723, Exp.: 06/30/2022

Class II Drugs Event

Event ID:
89992

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/11/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/05/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Torrent Pharma Inc
2091 Hartel Ave
Levittown PA United States

Distribution Pattern:
Nationwide in the U.S.A

Associated Products

Product Description:
Pantoprazole Sodium Delayed-Release Tablets, USP, 20 mg, Rx Only, 90 tablets per bottle, Manufactured by: Torrent Pharmaceuticals Ltd., Indrad-382 721, India, Manufactured for: Torrent Pharma Inc., Levittown, PA 19057, NDC# 13668-096-90.

Product Quantity:
24,888 bottles

Reason for Recall:
CGMP deviations: tablets cracking

Recall Number:
D-0852-2022

Code Information:
Lot #s: BA34G021, BA34G022, Exp. 09/2022

Class II Drugs Event

Event ID:
90021

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/15/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/05/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Dr. Reddy's Laboratories, Inc.
107 College Rd E
Princeton NJ United States

Distribution Pattern:
OH

Associated Products

Product Description:
Lansoprazole Delayed-Release Orally Disintegrating Tablets, 30 mg, 10 Packs of 10 Tablets each, 100 Tablets per blister pack, Rx Only, Distributed by: Dr. Reddy's Laboratories, Inc., Princeton, NJ 08540, Made in India, NDC 43598-561-78.

Product Quantity:
252 Blister Packs

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-0853-2022

Code Information:
Lot #: T2000645, Exp 07/2022

Class II Drugs Event

Event ID:
90037

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/15/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/03/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Macleods Pharma Usa Inc
666 Plainsboro Rd Bldg 200 Ste 230
Plainsboro NJ United States

Distribution Pattern:
Product was distributed nationwide.

Associated Products

Product Description:
Losartan Potassium Tablets, USP, 25 mg, a) 90-count bottles (NDC # 33342-044-10), b) 1000-count bottles (NDC # 33342-044-44), Rx Only, MFR: Macleods Pharma USA, Inc. Plainsboro, NJ 08536

Product Quantity:
12,408/90 count bottles; 1670/1000 count bottles =2,786,720 tablets

Reason for Recall:
CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits

Recall Number:
D-0832-2022

Code Information:
Lot # BLH2002A, exp. date 11/2022 BLH2003B, exp. date 11/2022 BLH2004A, exp. date 11/2022

Product Description:
Losartan Potassium Tablets, USP, 50 mg, a) 30-count bottles (NDC # 33342-045-07), b) 90-count bottles (NDC # 33342-045-10), c) 1000-count bottles (NDC # 33342-045-44), Rx Only, MFR: Macleods Pharma USA, Inc. Plainsboro, NJ 08536

Product Quantity:
3216/30 count bottles; 47,904/90 count bottles; 4269/1000 count bottles = 8,676,840 tablets

Reason for Recall:
CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits

Recall Number:
D-0833-2022

Code Information:
Lot # BLI2002A, exp. date 11/2022 BLI2004A, exp. date 11/2022 BLI2104B, exp. date 05/2023

Product Description:
Losartan Potassium Tablets, USP, 100 mg, a) 30-count bottles (NDC # 33342-046-07), b) 90-count bottles (NDC # 33342-046-10), c) 1000-count bottles (NDC # 33342-046-44), Rx Only, MFR: Macleods Pharma USA, Inc. Plainsboro, NJ 08536

Product Quantity:
3288/30 count bottles; 23,904/90 count bottles; 3364/1000 count bottles = 5,614,000 tablets

Reason for Recall:
CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits

Recall Number:
D-0834-2022

Code Information:
Lot # BLI2107B, exp. date 06/2023 BLI2101A, exp. date 12/2022 BLI2103A, exp. date 12/2022 BLI2105A, exp. date 05/2023

Product Description:
Losartan Potassium & Hydrochlorothiazide Tablets, USP, 50 mg/12.5 mg, a) 30-count bottles (NDC# 33342-050-07), b) 90-count bottles (NDC # 33342-050-10) c) 1000-count bottles (NDC # 33342-050-44), Rx Only, MFR: Macleods Pharma USA, Inc. Plainsboro, NJ 08536

Product Quantity:

Reason for Recall:
CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits

Recall Number:
D-0835-2022

Code Information:
Lot # BLK2107B, exp. date 05/2023 BLK2101A, exp. date 01/2025 BLK2102A, exp. date 02/2025 BLK2103B, exp. date 02/2023 BLK2103C, exp. date 02/2023 BLK2104A, exp. date 05/2023

Product Description:
Losartan Potassium & Hydrochlorothiazide Tablets, USP, 100 mg/25 mg, a) 30-count bottles (NDC# 33342-052-07), b) 90-count bottles (NDC # 33342-052-10) c) 1000-count bottles (NDC # 33342-052-44), Rx Only, MFR: Macleods Pharma USA, Inc. Plainsboro, NJ 08536

Product Quantity:

Reason for Recall:
CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits

Recall Number:
D-0836-2022

Code Information:
Lot # BLM2106B, exp. date 05/2023 BLM2101A, exp. date 01/2025 BLM2102A, exp. date 02/2023 BLM2106A, exp. date 05/2023 BLM2103B, exp. date 02/2023 BLM2104A, exp. date 05/2023 BLM2110A, exp. date 06/2023

Product Description:
Losartan Potassium & Hydrochlorothiazide Tablets, USP, 100 mg/12.5 mg, a) 30-count bottles (NDC# 33342-051-07), b) 90-count bottles (NDC # 33342-051-10) c) 1000-count bottles (NDC # 33342-051-44), Rx Only, MFR: Macleods Pharma USA, Inc. Plainsboro, NJ 08536

Product Quantity:

Reason for Recall:
CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits

Recall Number:
D-0837-2022

Code Information:
Lot # BLL2107B, exp. date 05/2023 BLL2101A, exp. date 01/2025 BLL2102A, exp. date 02/2025 BLL2103B, exp. date 02/2023 BLL2104A, exp. date 05/2023

Class II Drugs Event

Event ID:
90045

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/28/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/03/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Viatris Inc
1000 Mylan Blvd
Canonsburg PA United States

Distribution Pattern:
Product was distributed nationwide in the USA

Associated Products

Product Description:
alprazolam XR extended-release tablets, 3 mg, 60-count bottle, Rx only, Distributed by: Greenstone LLC, Peapack, NJ 07977, NDC 59762-0068-1.

Product Quantity:
6,789 bottles

Reason for Recall:
Failed Dissolution Specifications: low out-of-specification dissolution test results observed.

Recall Number:
D-0844-2022

Code Information:
Lot # EH8348, exp. date August 2023

Class II Drugs Event

Event ID:
90080

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/25/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/02/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
SCA Pharmaceuticals
755 Rainbow Rd Ste B
Windsor CT United States

Distribution Pattern:
Product was distributed nationwide within the United States

Associated Products

Product Description:
Norepinephrine 8mg in 0.9% Sodium Chloride 250 mL bag, Rx only, SCA Pharmaceuticals Windsor, CT 06095, NDC 70004-078-40

Product Quantity:
120 bags

Reason for Recall:
CGMP Deviations

Recall Number:
D-0829-2022

Code Information:
Lot #: 1222035815, Exp. Date 10-Jul-22

Product Description:
Fentanyl 2mcg/ml and Bupivacaine 0.125% in 0.9% Sodium Chloride 100 mL bags, Rx only, SCA Pharmaceuticals Windsor, CT 06095, NDC 70004-0231-32

Product Quantity:
424 bags

Reason for Recall:
CGMP Deviations

Recall Number:
D-0830-2022

Code Information:
Lot #: 1222035837, Exp. Date 22-Jul-22 Lot #: 1222035804, Exp. Date 25-Jul-22

Product Description:
Vancomycin HCl 1.5 g in 0.9% Sodium Chloride, 500 mL bags, Rx only, SCA Pharmaceuticals Windsor, CT 06095, NDC 70004-0924-44

Product Quantity:
30 bags

Reason for Recall:
CGMP Deviations

Recall Number:
D-0831-2022

Code Information:
Lot #: 1222035839, Exp. Date 09-Aug-22

Class III Drugs Event

Event ID:
89993

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/15/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/05/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Akorn, Inc.
1925 W Field Ct Ste 300
Lake Forest IL United States

Distribution Pattern:
Nationwide USA and Puerto Rico

Associated Products

Product Description:
Lidocaine Hydrochloride Oral Topical Solution, USP (Viscous) 2%, 100 mL per bottle, Rx only, Manufactured by Hi-Tech Pharmacal Co., Inc.

Amityville, NY 11701, NDC 50383-775-04

Product Quantity:
66,744 bottles

Reason for Recall:
Failed viscosity specification - product was below specificcation

Recall Number:
D-0846-2022

Code Information:
Lot #: 370978, Exp 9/30/2022

Not Yet Classified Drugs Event

Event ID:
89802

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/29/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Best Brands Consumer Products, Inc.
20 W 33rd St
New York NY United States

Distribution Pattern:
Nationwide in the US

Associated Products

Product Description:
Mickey Mouse Hand Sanitizer, ethyl alcohol 68%, 2.11 oz./to mL bottle, Best Brands Consumer Products, Inc., c/o Best Brands Sales Company LLC, New York, NY NDC 74530-013-02

Product Quantity:
44,640 bottles

Reason for Recall:
Chemical Contamination; FDA analysis found product to contain methanol

Recall Number:

Code Information:
Lot # 20D21, exp. date 06/30/2022

Product Description:
The Mandalorian Hand Sanitizer, ethyl alcohol 68%, 2.11 oz./60 mL bottles, Best Brands Consumer Products, Inc., c/o Best Brands Sales Company LLC, New York, NY NDC 74530-012-02

Product Quantity:
346,320 bottles

Reason for Recall:
Chemical Contamination; FDA analysis found product to contain benzene

Recall Number:

Code Information:
Lot # 20E21, exp. date 09/30/2022